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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/783,474	02/14/2001	Stephen H. Friend	9301-129	1718

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EXAMINER	
MARSCHEL, ARDIN H	
ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 02/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/783,474	FRIEND ET AL.	
	Examiner	Art Unit	
	Ardin Marschel	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51-59* is/are rejected.

7)☒ Claim(s) *1-50 and 60-69 have been canceled.* [illegible].

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election of Group II (claims 51-59) in Paper No. 6, filed 10/4/02, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

PRIORITY

If applicants desire priority under 35 U.S.C. §120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. It is noted that this appears as the first sentence of the specification following the title. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed on or after November 29, 2000, any claim for priority must be made during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2) and (a)(5). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is

accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) a surcharge under 37 CFR 1.17(t), and (2) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Commissioner may require additional information where there is a question whether the delay was unintentional. The petition should be directed to the Office of Petitions, Box DAC, Assistant Commissioner for Patents, Washington, DC 20231.

TITLE

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title includes both monitoring of disease states as well as therapies, whereas, in contrast, only methods of diagnosing a subject using response profiles are presently claimed.

ABSTRACT

The abstract of the disclosure is objected to because it exceeds 150 words. A replacement abstract on its own separate sheet of paper is required. Correction is required. See MPEP § 608.01(b).

VAGUENESS AND INDEFINITENESS

Claims 51-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 51, line 3, and elsewhere a limitation directed to "interpolated" response profile is set forth. The metes and bounds of interpolation practice are vague and indefinite. Is this limitation directed to estimation of data error bars? Is this limitation directed to the formation of curves, or curve fitting, which relate raw data to an assay value for cellular constituent level? Since response profiles contain plural data values is interpolation the method of combining these multiple values into an overall weighted value for final diagnosis? It is noted that there is no distinct definition in the specification regarding what interpolation practice is meant to be. It is additionally noted that curve fitting for assay calculations is described in the specification starting, for example, on page 30, line 13, but without clearly defining curve fitting of assay standardization curves as interpolation. Is the interpolation meant to be the practice by which complex response profiles are related to disease levels? These various interpretations of interpolation are different and thus causes unclarity as to what interpolation practice is actually meant as defining this limitation. Clarification via clearer claim wording is requested. Claims 52-59 also contain this unclarity due to their dependence directly or indirectly from claim 51.

PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-

> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 51-53, 56, and 57 are rejected under 35 U.S.C. 102(b) and (e)(2) as being clearly anticipated by Swift et al.(P/N 5,464,742) or, alternatively, under 35 U.S.C. 102(e)(2) by Anderson et al.(P/N 6,267,722).

Swift et al. summarizes in the abstract that the invention therein disclosed is directed to the testing of associations between a gene allele and a disease, thus being deemed to be directed to disease diagnosis as is the instant invention. Families are analyzed in order to define response profiles for plural alleles of genes as they relate to diseases as described in column 5, lines 3-67, and column 7, line 10, through column 8, line 60. The usage of statistical methods for this analysis is disclosed in column 8, lines 44-60, to find the best fit of minimized difference (maximum correlation) between the data and a diagnostic result. Different levels of the disease as related to gene alleles is described in column 8, line 66, through column 9, line 28. Some possible levels are homozygous normal, homozygous abnormal, and heterozygous, known commonly as a carrier of a disease allele. Statistics are further described in column 9, line 30, through column 14, line 11, which includes equations utilized in curve fitting of data and thus discloses interpolation as a possible interpretation of what interpolation of response profiles is. See the above rejection based on unclarity of this issue under 35 U.S.C. § 112, second paragraph. The assessment of a 95% confidence level of a disease state

is disclosed in column 14, lines 51-56, which also correlates this level with a heterozygote breast cancer level of disease vs. someone who does not carry the allele. This analysis of a plurality of alleles such as heterozygous vs. homozygous is reasonably a response profile as instantly claimed. Thus, Swift et al. develops interpolated response profiles which statistically permits the determination of diseases levels from said profiles including diagnosing 95% confidence or statistical significance regarding said disease level diagnosis thus anticipating the above listed claims of the instant invention.

Similar to Swift et al., the disclosure of Anderson et al. assays cellular constituents to generate disease correlated interpolated response profiles for diagnosis. See, for example, response profile testing in column 2, lines 8-67. Also, note curve fitting or interpolation in column 2, lines 39-51, and column 23, line 16, et seq. to minimize differences (maximize correlation) between response profile data and proper disease diagnosis. The disease levels or severity as assessed as noted in column 9, lines 11-15. The weighting of data values for response profile interpolation as a possible interpretation is set forth in Anderson et al., in column 8, lines 23-33. 95% confidence levels for response profiling is set for specifically for at least one test in column 14, lines 23-41. Thus, Anderson et al. equivalently anticipates the above listed instant claims.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the

notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

February 4, 2003

ARDIN H. MARSCHEL
PRIMARY EXAMINER